

a centralized point for each manufacturer or distributor within the United States.

[58 FR 43447, Aug. 16, 1993, as amended at 65 FR 43690, July 14, 2000]

§ 821.55 Confidentiality.

(a) Any patient receiving a device subject to tracking requirements under this part may refuse to release, or refuse permission to release, the patient's name, address, telephone number, and social security number, or other identifying information for the purpose of tracking.

(b) Records and other information submitted to FDA under this part shall be protected from public disclosure to the extent permitted under part 20 of this chapter, and in accordance with § 20.63 of this chapter, information contained in such records that would identify patient or research subjects shall not be available for public disclosure except as provided in those parts.

(c) Patient names or other identifiers may be disclosed to a manufacturer or other person subject to this part or to a physician when the health or safety of the patient requires that such persons have access to the information. Such notification will be pursuant to agreement that the record or information will not be further disclosed except as the health aspects of the patient requires. Such notification does not constitute public disclosure and will not trigger the availability of the same information to the public generally.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002]

§ 821.60 Retention of records.

Persons required to maintain records under this part shall maintain such records for the useful life of each tracked device they manufacture or distribute. The useful life of a device is the time a device is in use or in distribution for use. For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use, has been explanted, returned to the manufacturer, or the patient has died.

PART 822—POSTMARKET SURVEILLANCE

Subpart A—General Provisions

Sec.

822.1 What does this part cover?

822.2 What is the purpose of this part?

822.3 How do you define the terms used in this part?

822.4 Does this part apply to me?

Subpart B—Notification

822.5 How will I know if I must conduct postmarket surveillance?

822.6 When will you notify me that I am required to conduct postmarket surveillance?

822.7 What should I do if I do not agree that postmarket surveillance is appropriate?

Subpart C—Postmarket Surveillance Plan

822.8 When, where, and how must I submit my postmarket surveillance plan?

822.9 What must I include in my submission?

822.10 What must I include in my surveillance plan?

822.11 What should I consider when designing my plan to conduct postmarket surveillance?

822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?

822.13 [Reserved]

822.14 May I reference information previously submitted instead of submitting it again?

822.15 How long must I conduct postmarket surveillance of my device?

Subpart D—FDA Review and Action

822.16 What will you consider in the review of my submission?

822.17 How long will your review of my submission take?

822.18 How will I be notified of your decision?

822.19 What kinds of decisions may you make?

822.20 What are the consequences if I fail to submit a postmarket surveillance plan, my plan is disapproved and I fail to submit a new plan, or I fail to conduct surveillance in accordance with my approved plan?

822.21 What must I do if I want to make changes to my postmarket surveillance plan after you have approved it?

822.22 What recourse do I have if I do not agree with your decision?

822.23 Is the information in my submission considered confidential?